Technical Memorandum

Summary of Comments on the Risk Assessment Document for Sandy Smelter, Utah

U.S. Environmental Protection Agency

Technical Review Workgroup for Lead

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Risk Assessment Document for Sandy Smelter, Utah

The comments outlined in this review are the result of an ongoing dialogue between EPA Region 8 staff and the Technical Review Workgroup (TRW) on the Risk Assessment for the Sandy Smelter, Utah, Superfund site. The Sandy Smelter risk assessment was developed in December 1995 and is expected to be the basis for a final remedy for the site. The TRW is a scientific advisory group to the Superfund program, whose responsibilities (as outlined in the lead administrative reform memo and the short sheet on consultation) include reviewing any risk assessment that is expected to set a precedent or that derives a Preliminary Remediation Goal (PRG) outside of the range of 400-1,200 ppm based on the application of the Integrated Exposure Uptake Biokinetic (IEUBK) Model. TRW reviews and recommendations are advice that is intended to improve the technical quality of risk assessments.

· The purpose of this review is to improve the technical approach of the risk assessment, identify areas where clarification in guidance is needed, and identify approaches that are likely to lead to inconsistent lead risks assessments at other sites. To support the preparation of this review, Region 8 staff provided important information on the Sandy Smelter Risk Assessment. The TRW appreciates the efforts of Region 8 staff in contributing to this review.

The general finding of the TRW is that some of the IEUBK Model inputs used in the Sandy Smelter risk assessment were not sufficiently developed for the uses to which they were applied. The TRW believes that this review also has identified areas where EPA should update and clarify existing guidance to promote consistent application of the IEUBK Model.

The comments of the TRW on the Sandy Smelter risk assessment are presented in this document and summarized in Table 1. The table also includes Region 8's response to each of the comments, which Region 8 staff plan to include in a risk assessment addendum. Other risk assessment and risk characterization comments on subjects that were not part of the Sandy Smelter risk assessment document have been provided to Region 8 in a companion document.

As outlined in the table, Region 8 staff have agreed to provide additional information in a risk assessment addendum that will update information in the risk assessment. The TRW recognizes that different technical interpretations are part of the normal scientific process. In this spirit, the TRW agrees with Region 8 staff that some clarification of the guidance for the application of the IEUBK Model is warranted. An example is methods for sampling dust (the TRW has not provided recommendations on the several methods available). In addition, there are some areas of guidance that need to be reviewed and updated. Examples of areas that the TRW intends to address are the new

FDA information on lead in diet and the use of blood lead data in risk assessment.

The TRW believes that this review has been constructive for sharing information, promoting sound scientific analysis, and improving upon the consistency of the application of the IEUBK. In the sections that follow, some additional information on the areas summarized in the table are presented. Detailed technical information supporting comments provided by the TRW is presented in the Appendix.

Geometric Standard Deviation (GSD)

The TRW concludes that the GSD value of 1.4 may be too low and that support for 1.4 as a point estimate for GSD is not strong enough to recommend deviating from the 1.6 default value. The TRW's first concern is that weighted estimates of blood lead variability, taking into account the number of children in each residential soil lead-dust lead box, resulted in GSD estimates of 1.5 to 1.6. The second concern is that the population of children who live at the Sandy Smelter site may be more homogeneous with respect to demographic and socioeconomic factors that affect the variability in blood lead concentrations within populations. The third concern is that blood lead concentrations in the period of late October and early November may have been lower than the peak blood lead period of August-September. This variability is combined with seasonal variability that is evident at other sites. While the TRW concludes that the support for the GSD of 1.4 is not sufficient to support replacement of the default GSD, the TRW believes that the risk assessment also should show risk estimates based on a GSD of 1.6.

Region 8 has indicated that "the GSD of 1.4 was based on a well-conducted blood lead study, using conventional statistical techniques, and appropriately characterizes the variability at the site." Differences in scientific judgement between Region 8 and the TRW largely derive from differences in interpretation of the University of Cincinnati (UC) blood lead study, specifically the degree of confidence that can be placed in the results of this study and the statistical confidence that can be placed in this study, and other issues (e.g., sampling period for blood lead). These issues will be addressed in upcoming guidance materials that will focus on these issues as they relate to blood lead studies.

Empirical Comparisons

The empirical comparisons presented do not conform with the approach recommended by the TRW in the 1994 Validation Strategy. The TRW utilized the latter strategy in a reanalysis of the UC Sandy data and found that the observed geometric mean (GM) blood lead concentration and that predicted by the IEUBK Model differed by less than 1 μg/dL. Given limitations of the blood lead study and the results of the empirical comparisons presented here, the TRW concludes that the available data do not indicate that the IEUBK Model overestimates blood lead concentrations for this site. The reasons for this conclusion are provided below.

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Well-conducted and carefully interpreted blood lead studies can provide an important indicator of the magnitude of current population risk from lead exposures in a community. The availability of adequate documentation of study methods and results[1] is essential for an evaluation of data from blood lead studies. The TRW recommends that the Sandy risk assessment specifically document that such information related to the University of Cincinnati (UC) study conducted in Sandy is available. The TRW identified the following issues regarding the interpretation of the results of the UC study:

(1)   The blood lead samples in the study were collected in the fall months (October/November). Experience with other populations indicates that there are substantial fluctuations in blood lead levels by season, and levels in October and November are likely to be substantially below levels that would be observed in the peak summer months. The causes for seasonal patterns in blood lead levels are not well understood, but may include physiological and behavioral changes. Such changes have been observed in various studies (e.g., *The Urban Soil Lead Abatement Demonstration Project* [EPA/600/P-93/001aF]). Therefore, the observation that the weather was generally mild in the period in which the blood lead data were collected does not diminish concerns that the observed blood lead levels may have been low relative to other times of the year.

(2)   While a final timetable for the UC study was not available to the TRW, it appears that UC field staff had substantial contact with study families well before blood samples were drawn. This raises the concern that the interviewing process would have served to alert the respondents to lead risk in Sandy and through questioning about hygiene and home conditions might have promoted actions that would tend to reduce those risks. There is evidence that individual level contact with parents is important to the success of intervention efforts; this study may have implicitly included an important individual level intervention component.

(3)   Taken at face value, the UC blood lead data provides little information on risks to children exposed to higher soil lead levels (e.g., 1000 ppm and above). Only a small fraction of study participants had yard soil levels above 1000 ppm, and, therefore, the study results do not provide direct, meaningful information about risk to individuals exposed to high concentrations of soil lead. The UC study can probably be interpreted as indicating that there is not a widespread, severe problem with environmental lead exposures to children in Sandy; that is consistent with the environmental sampling data that also indicate that the most typical lead exposures in Sandy are not high.

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[1] The written documentation for a blood lead study would include final study protocols, completed quality assurance documentation (for blood and environmental lead measurements), and adequately reviewed written reports of study findings.

Additional blood lead data for Sandy has been recently provided though screening surveys conducted by the WIC program. These data, while reassuring in that Sandy does not appear to have a widespread, severe problem with environmental lead exposures, are extremely difficult to interpret in terms of risks to the limited subset of children in Sandy who live on properties with higher levels of lead contamination (e.g., 1000 ppm and above). No paired environmental lead samples were collected in conjunction with the WIC blood lead screening, therefore, the levels of lead to which the participants were exposed is not known. Unfortunately, data on residence locations for the screened children also are not available, so that EPA data on the distribution of contamination in Sandy cannot be used in interpreting the WIC data. Finally, only a rather small number of children were sampled in the WIC effort, which also restricts inferences that might be drawn from that data.

Other Issues

Bioavailability

The TRW agrees with Region 8 staff that there is not enough site-specific data to support replacing the default value of 30%. Based upon the limited data from the rat study and geochemical characterization data, there is uncertainty as to whether the bioavailibility may be higher or lower than the default. The TRW appreciates that Region 8 staff report that they believe that the geochemical speciation evidence strongly suggests that lower bioavailability is more plausible. While the TRW acknowledges that this might be correct, the TRW has not received any analysis or written documentation to distinguish this site in terms of geochemical speciation from any other lead site. In the absence of objective support, the TRW concludes that it is equally plausible that the default value of 30% is an overestimation or underestimation of the actual bioavailability of lead in Sandy site soil.

Gardening

The TRW expressed concern that because of the makeup of the population of the Sandy City site (including many families who grow a significant portion of their consumed vegetables), consumption of home-grown vegetables may result in a larger lead intake from dietary sources than might be expected at other sites. The risk assessment lacks objective support for the statement that the vegetable pathway is unlikely to be significant. The TRW suggests that the uncertainty section address this issue by modifying the discussion to be more general, as in the discussion offered in the Kennecott risk assessment. If uptake of lead by homegrown vegetables is similar to that seen at Bingham Creek (Kennecott), the analysis developed for that site suggests that lead consumed in garden vegetables would probably not constitute a problem if this were the only pathway of exposure. However, there may be households in which lead contributed by garden vegetable consumption is enough to create a risk level of concern when combined with that from other pathways. In other cases, it may simply increase the level of concern.

Quality Assurance/Quality Control

Based upon the information provided by Region 8 staff, the TRW concludes that the strength of the risk assessment would be improved by referencing relevant information on quality assurance/quality control. For example, it is our understanding that the EPA environmental analytical data is supported by quality assurance/quality control information that is equivalent to that of the Contract Laboratory Program; also the TRW was unclear what QA data was available to support the UC environmental sampling. Such information enhances the credibility of the risk assessment and should not be lost.

Table 1. Summary of Recommendations Provided by the TRW for the Sandy Smelter Risk Assessment

Issue	TRW Comment	Region 8 Staff Response
Development of the GSD	Because of the TRW's concerns about the blood lead study and the statistical methods used in the calculation of the GSD, the TRW recommends that the calculated GSD of 1.4 not be used to replace the default GSD of 1.6 recommended in guidance. The calculated GSD of 1.4 provides some information that may be useful for characterizing uncertainties in the default GSD.	Region 8 staff believe that the GSD of 1.4 was based on a well-conducted blood lead study, using conventional statistical techniques, and appropriately characterizes the variability at the site. Region 8 staff plan to prepare an addendum to the risk assessment which will reflect the TRW's concerns about the GSD parameter and the impact that the default GSD will have on the site risk estimates and PRGs.
Empirical Comparisons	The TRW has undertaken some comparisons between the observed and predicted blood lead concentrations in Sandy and concludes that there is general concordance between IEUBK Model predictions and the UC blood lead study, given the limitations of the UC study. The TRW recommends that the statement in the risk assessment, "unresolved differences between the blood lead levels predicted by the IEUBK model ... and the measured blood lead levels introduces a significant uncertainty into the risk assessment" (p. 23) be deleted from the risk assessment.	Region 8 staff will include in the risk assessment addendum the results of the TRW's empirical comparisons between predicted and observed blood lead concentrations in the "stay-at-home" children.

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Issue	TRW Comment	Region 8 Staff Response
Bioavailability	The TRW agrees that the use of 30% as the default is appropriate for the Sandy site. Based on the data cited in the risk assessment, the TRW recommends that uncertainty analysis should indicate that higher bioavailability is as plausible as lower bioavailability. While information characterizing the physical properties of soils was provided, an update on the research undertaken to support the conclusion of lower bioavailability was not available to the TRW as part of this review.	Region 8 staff disagree with the statement that the uncertainty analysis should indicate that higher bioavailability is as plausible as lower bioavailability. Region 8 staff maintain that the geochemical speciation evidence strongly suggests that lower bioavailability is more plausible.
Lead Intake from Home Gardens	The TRW notes that the assessment of another Region 8 site in Utah (Kennecott) has concluded that lead intake from garden vegetables may contribute to overall lead exposure of residents. The TRW recommends that the Sandy risk assessment revisit the discussion of this parameter and provide an evaluation of the significance of this pathway.	Region 8 staff will include a discussion in the addendum which more fully discusses the results of the Bingham Creek plant uptake study and the signficance of this exposure pathway.
Quality Assurance/Quality Control	The TRW recommends that Region 8 reference existing documents on QA/QC to improve the support for the risk assessment (e.g., University of Cincinnati environmental data).	Region 8 staff agree with the TRW on referencing documents.

APPENDIX

1.0   EVALUATION OF EMPIRICAL COMPARISONS

1.1   Overview

The Sandy site risk assessment included a comparison of IEUBK Model predictions with blood lead levels observed in the study of children in Sandy, Utah, that was conducted by the University of Cincinnati (UC). While the previous section discusses a number of issues that would argue against placing weight on the blood lead findings, the TRW felt that the numerical comparisons presented in the Region 8 report warranted further consideration. The TRW verified the overall numerical results reported by the EPA's Sandy site contractor, which were that the geometric mean blood lead level predicted by the IEUBK Model was approximately 2 μg/dL higher than the geometric mean of the blood lead levels observed at the site, using all of the raw data as in the EPA contractor report. These Model predictions were based on the average of all available soil measurements, one composite dust measurement, and "at-tap" water measurements. We will discuss three factors that limit the usefulness of this observation:

- Use of partially flushed water in IEUBK Model simulations
- Focus on children with more representative lead exposure inputs
- Quality assurance data and analytical variability

When changes to the analysis are made to address these factors, and all other non-site-specific inputs are left at default levels, IEUBK predictions are within 1 μg/dL of measured geometric mean blood lead concentrations, with concordant exceedence probabilities.

1.2   Impact of additional information on IEUBK predictions

1.2.1   Use of first draw tap water in IEUBK Model simulations

According to the work plan, water samples were collected after a 3-minute flush and 30-minute stagnation period. This is neither first draw nor fully flushed. Also, the TRW observed that it seemed unusual that water lead concentrations were reported only at 5 μg/L or 10 μg/L; a concern was raised about whether or not some of the reported concentrations actually were below the detection limits. The TRW ran IEUBK Model simulations assuming that daily water intake consisted of 50% of this partially flushed measurement, using 2.5 μg/dL as half of the limit of detection where appropriate, and 50% flushed water, assuming that flushed water had a lead concentration of 1 μg/L (U.S. EPA, 1992). These assumptions decreased the predicted blood lead levels by ~0.5 μg/dL for the 15 children who were exposed to 10 μg/L measurements. Although water lead appeared not to be a major concern in Sandy (i.e., children exposed to higher water lead concentrations had

slightly lower blood lead levels than children exposed to lower water lead concentrations, all other factors assumed to be equal), the TRW concluded that use of the unadjusted measurements as input to the IEUBK Model contributed to overestimation of predicted blood lead levels, especially in view of the much lower water lead levels inferred from the later EPA study.

1.2.2 Representative lead exposure inputs

The TRW noted that empirical comparisons of observed and predicted blood lead levels must be carried out in a manner where the environmental measurements can be reasonably expected to correspond to children's actual exposure. Several variables available in the data set provide some of this information:

- Play area soil measurements should be useful, because play areas were identified as areas where these children were likely to spend their time.[2]

- Children who spend several hours each day away from home have less exposure to the lead measured at their homes. Overall, about 50% of the 105 children sampled spent more than 2 hours each day away from home, including traveling and playing in other parts of their neighborhoods. This is similar to the results of surveys at other sites conducted by ATSDR (ATSDR, 1995), although Sandy children used day care much less than children at these other sites did.

Based on the above considerations, subgroup geometric mean blood lead levels that apply to children who are exposed to the measured play area soil lead levels, and who play outside, are presented in Table 1. These results are consistent with other empirical comparisons of IEUBK Model predictions with site-specific epidemiologic data (Galena/Jasper, Granite City, Palmerton, Rochester). In those analyses, use of input values for children who were exposed in play areas and who were away from home less than 10 hr/wk (roughly equivalent to 2 hr/day) yielded predicted geometric mean blood lead levels that were within 1 μg/dL of the observed geometric mean observed blood lead levels (U.S. EPA, 1996).

Generalizations drawn from comparing the observed blood leads across "time-away" groupings can be misleading without more information about environmental lead levels at the other locations. The primary finding of these comparisons is that the predicted

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[2]Note that in the UC study a single soil sample was collected to represent sandbox and play area exposures. While a sandbox may contribute to a child's overall exposure to dirt and lead, the TRW would recommend that in future work, separate samples be collected to represent sandboxes (if needed) and play areas. If appropriate, data for both types of samples could be used in constructing a weighted average soil concentration.

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blood lead concentrations were closest to observed concentrations in the subset of children who spent most of their time at home, where the environmental lead levels were measured.

1.2.3 Quality Assurance data and analytical variability

The results in the quality assurance report for blood lead samples demonstrate analytical variability that is similar to the experience of CDC (D. Paschal, personal communication). The University of Cincinnati reported a standard deviation of 0.5 for the analysis of CDC blood lead standards. This value is slightly higher than that observed in the CDC laboratory analysis for the ATSDR/EPA Multi-site Study (Galena/Jasper, Granite City, Palmerton), which indicated a standard deviation of approximately 0.44, assuming normal, rather than lognormal, variability.

This source of variability, if unbiased, has no effect on the estimation of mean blood lead levels, but does affect the estimate of the probability of exceeding a given blood lead level. The TRW estimated the probability of a blood lead level exceeding 10 μg/dL from the observed blood lead data. This analysis included all measurements that were reported as less than 1.4 μg/dL, even though the quality control report indicated that the limit of detection was 1.4 μg/dL, rather than omitting the samples or imputing a midpoint between zero and the limit of detection. The probabilities for exceeding 10 μg/dL are shown in Table 2. These do not allow for analytical variability or other influences affecting the estimation of the "true" blood lead level for each child, such as seasonality or increased parental attention following interaction of the investigators with the community.

The confidence interval for the IEUBK-based estimate is wider than that derived from the blood lead study. Given the other influences on blood lead measurements that were not quantified, and should not be ignored in this type of comparison, the agreement between probabilities of exceeding 10 μg/dL based on observed and predicted blood lead levels is remarkably close.

These results are qualitatively similar to those seen in empirical comparisons made between IEUBK Model predictions and epidemiologic data from the Palmerton and Leadville sites, which were collected by the same University of Cincinnati investigators. In these comparisons, play area measurements generally were associated with the lowest of the soil measurements reported for each residence, and the play area measurements resulted in overall predictions that were in closest agreement to the observed estimate of the probability of exceeding 10 μg/dL.

1.3 Summary of empirical comparisons

Analyses similar to the empirical comparisons included in the Sandy site risk assessment underscore the importance of distinguishing between an evaluation of the plausibility of Model predictions, and generating predictions to be used in risk assessment. In an evaluation of Model plausibility, the central issue is: Given well-characterized contact with environmental lead and the limitations, uncertainties, and other caveats associated with the observations and the Model, does the predicted blood lead distribution agree with the

observed blood lead distribution? In assessing risk, however, the issue is: What is the probability that current environmental lead levels will result in a blood lead level exceeding a given value, in any child, not just the children currently at the site?

When the IEUBK modeling focused on children with representative exposure measurements (i.e., those who spent less than 2 hours each day away from home) there was a reasonably close agreement (within 0.6 μg/dL) between geometric mean observed and predicted blood lead levels, and between proportions expected to be above 10 μg/dL. This result agrees with the work already carried out with the Multi-site study (ATSDR, 1995) and the Rochester Lead in Dust study. These observations also support the observation from other studies that residential measurements cannot be relied on to capture the range of individual children's lead exposures for half of each data set examined so far (i.e., the 50% who spent more than 2 hours each day away from home).

Given that the IEUBK Model has provided useful predictions from data with relatively well-characterized exposure, the Model can be relied upon to estimate risk of elevated blood lead in more generalized circumstances, for which relevant blood lead measurements are not available. In this framework, the inputs to the Model should focus on more general exposure scenarios relevant to current or future site use. For example, play areas such as those identified in this study may not be the play areas that children use the next season, due to the dynamics of children's activities as they mature, family size, and turnover of residences, among other factors. The data collected in all of the yards in the study provide valuable information on the range of soil concentrations that may characterize future uses of the yards and neighborhoods.

**Table 1. Blood Lead Levels in Children Stratified by
Time Spent Away from Home**

Away from Home (hrs/day)	Sample Size	Blood Lead GM (95% CI) (μg/dL)	
		Observed	Predicted
<2	27	3.1 (2.5, 3.9)	3.8 (3.4, 4.3)
≥2	37	3.2 (2.6, 3.8)	4.3 (3.7, 5.1)

Table 2. Probability of Exceeding 10 μg/dL Based on Observed or Predicted Blood Lead Concentrations

Children with play area soil lead measurements, and who are away from home less than 2 hr/day (n=27)	Probability of Exceeding 10 μg/dL (95% CI)	
	Based on Observed	Based on Predicted (GSD=1.6)
	0.0 (0.0, 0.13)	0.04 (0.0, 0.18)

2.0 Blood lead data used in the empirical comparisons

Concern for lead-related risks at the Sandy Smelter site has focused on homes with very high soil lead concentrations. However, much of the soil in the study area is not contaminated at these high concentrations, and most of the dust in homes studied in the UC study do not have high lead concentrations. The median soil lead concentration in the study was 332 μg/g (average of all yard samples for the 105 homes in the study data base with at least one yard soil measurement). Furthermore, only 11 homes had mean soil lead concentrations above 1000 μg/g, only 6 were above 1200 μg/g, only 3 were above 2000 μg/g, and only 1 home was above 2500 μg/g. (The latter home had only a single soil sample reported; that sample showed a perimeter concentration of 4400 μg/g. Perimeter values are frequently higher than other samples and may contain lead paint material from the house.) Thus the study includes few homes with soil lead levels above 1000 μg/g and provides no interpretable data on risks of elevated blood lead levels at higher soil concentrations. Accordingly, while the study results indicate that at the time of the study the participants as a group did not experience markedly elevated blood lead levels, the information provided does not include information to evaluate risks to show locations of homes whose soil exposures are particularly high (e.g., those above 1000 μg/g). In the absence of such information it is not possible to see if there are any visual patterns that support agreement between elevated blood lead levels and elevated soil lead levels.

While the majority of children in Sandy may be exposed to relatively low concentrations of soil lead, environmental risk concerns need to include a focus on those children whose exposures are above the norm. Aggregate population data for a community can effectively obscure risks to children who are highly exposed to lead.

2.1 Seasonal effects on blood lead

Children's blood lead levels have historically been observed to follow strong seasonal patterns, with peak levels being seen in the summer months. As a prominent example, strong seasonal effects were observed in the Boston longitudinal study (Seasonal rhythms of blood lead levels: Boston, 1979-1983, USEPA September 1995. EPA 747-R-94-003). In this study, peak blood levels were seen in June and exceeded minimum blood levels seen in winter by more than a factor of two. It is noteworthy that by September blood lead levels were already much reduced from their summer peak. This study also noted seasonal patterns in measured environmental lead levels including air and dust lead. The analysis suggested that the variability in the environmental levels contributed to the observed seasonality in blood lead levels. At this time, however, it is not possible to ascribe the observed seasonality in blood lead levels to any single factor and it is likely that a number of factors contribute. These factors may include changes in children's behavioral patterns such as time spent outdoors, changes in dust lead or other environmental lead measures, and physiological changes with season, including, for example an effect of sunlight on vitamin D synthesis (increased levels of vitamin D are known to contribute to increased absorption of ingested lead). For the purposes of this review it is sufficient to recognize that while the complex and multifactorial nature of seasonality in blood lead levels is not yet well understood, the existence of the pattern is well documented. The TRW strongly .recommends that blood lead measurement studies be conducted in the peak summer months as is discussed in the IEUBK guidance document.

In the UC Sandy study, blood lead samples were predominantly collected in October and November, and may be anticipated to have been substantially lower than the peak summer values. We understand that Sandy experienced relatively warm weather during the UC study period. However, for the reasons noted above, that observation does not contravene our concern that seasonal effects may have substantially reduced the observed blood lead levels.

2.2   Mismatch between environmental and blood lead sampling

There was also a seasonal mismatch between the environmental sampling and blood lead sampling in Sandy. The environmental sampling occurred in the summer and the blood lead sampling occurred later, primarily in October and November. Seasonal trends in lead levels have been observed for both blood lead and environmental lead levels where both dust lead levels and blood lead levels tend to peak in the summer (see, for example, the Boston longitudinal study shown below). While the conduct of a blood lead study in the autumn may have resulted in the observation of lower blood lead levels, a somewhat more subtle effect may have affected the empirical comparisons with the IEUBK Model predictions. For example, if dust lead levels were higher in the summer during environmental sampling, IEUBK Model runs made with these data may be expected to yield an over-prediction of blood lead levels measured in the autumn. Thus, the lack of temporal pairing of the environmental and blood sampling could have significant impacts when the study results are used for Model comparisons.

The TRW urges that in future studies blood and environmental data should be collected simultaneously. Studies should focus on the peak summer months when blood lead levels are generally elevated, and in observational studies, prior contacts that implicitly inform participants

about the nature of lead hazards and actions that may reduce those hazards should be avoided.

Boston longitudinal study, seasonal pattern in blood lead levels

Month of year
Seasonal effect, adjusted for age and date of birth
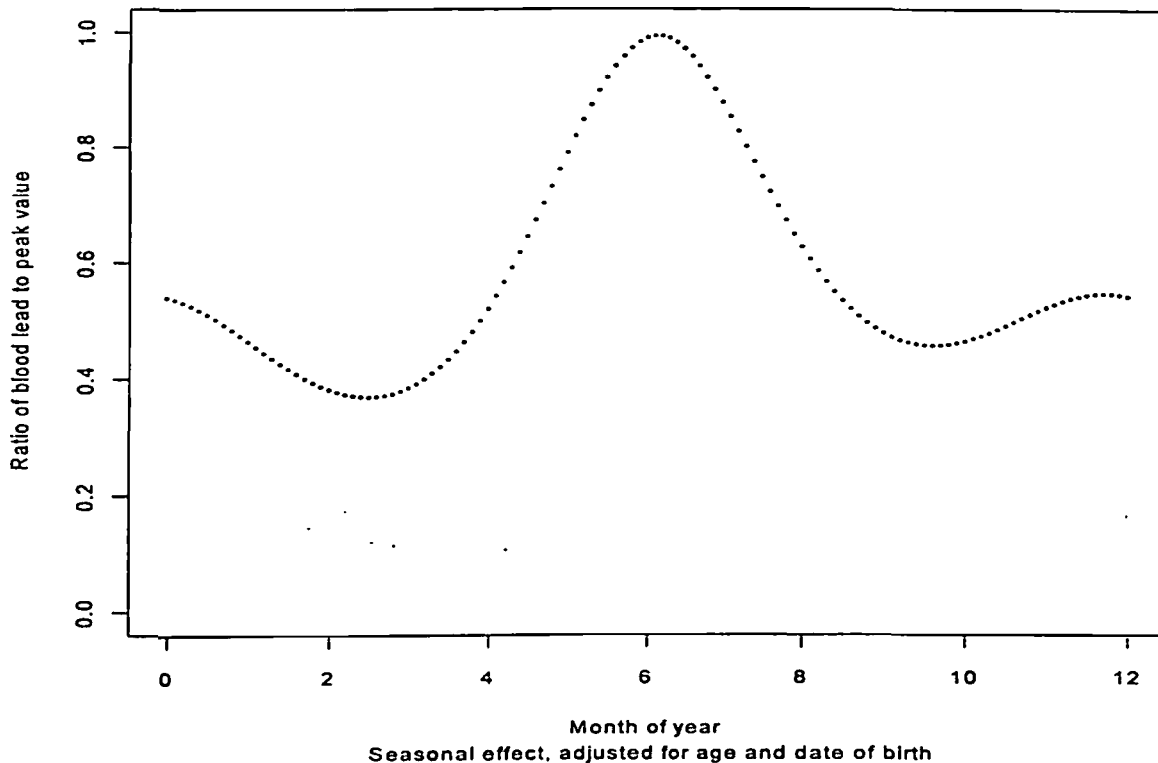
However, controlled intervention studies to determine whether the provision of information to parents can aid in reducing children's blood lead levels are encouraged as more data are needed to determine the effectiveness of these approaches in reducing lead exposures in children.

3.0   EFFECT OF SAMPLING METHODOLOGY ON ESTIMATED DUST TO SOIL RATIO

The TRW noted that there appear to be differences in the dust/soil mass ratios seen in Sandy in the University of Cincinnati study and in the sampling conducted by EPA Region 8. As shown in Table 3, the EPA data generally showed lower dust to soil ratios than did the UC data. These differences may have been influenced by the dust sampling methodology, as the UC study utilized a low flow cassette filter sampling device while the EPA work utilized a method based upon a high volume air sampler. The higher air flow in the EPA device may have led to collection of different dust material, including coarser materials, than would the low flow UC device. It is plausible that coarser material may have lower lead content than would fine dust. In general the fine dust material is believed to be more relevant to assessing children's exposures to lead in dust, as such exposures are thought to occur primarily through hand/mouth contact and

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other incidental mouthing activities. Therefore, there is reason for concern that the dust data obtained from the high volume samplers may understate dust concentrations for risk assessment applications. As noted previously, the TRW has concerns about the adequacy of reporting and quality assurance with the UC data set. However it is noteworthy that 44% of the observed soil/dust ratios in the UC data set equaled or exceeded the IEUBK Model default of 0.7.

Table 3. UC and USEPA observations on dust to soil ratio in Sandy Smelter, UT

Percentile of data	10%	20%	30%	40%	50%	60%	70%	80%	90%
UC dust/soil ratio	0.33	0.42	0.47	0.55	0.60	0.77	0.89	1.18	1.48
USEPA dust/soil ratio	0.11	0.17	0.20	0.22	0.26	0.31	0.38	0.46	0.60

3.1 Statistical measurement error in estimating the dust to soil ratio

In previous reviews, and particularly in the review of the Leadville adult lead risk assessment, the TRW has stressed the importance of statistical measurement error in estimating the dust to soil concentration ratio. The Sandy risk assessment did not provide adequate details on the approach used to estimate the dust to soil ratio for Sandy, except that a regression technique was used to relate household dust lead to soil lead. As there is likely to be substantial measurement error in the household soil concentration (the independent variable), a regression analysis will understate the magnitude of the dust to soil relationship. This problem was not discussed in the Sandy risk assessment, and it is likely that a measurement error effect has contributed to underestimation of a dust to soil ratio for Sandy. The TRW recommends that Region 8 reexamine the Sandy data on the dust to soil relationship. In Leadville, the TRW recommended that one way around this problem is to compare average dust concentrations to average soil concentrations for homes where lead paint is unlikely to be an important source of lead in house dust. That approach may prove viable for Sandy. The ratio of the mean dust concentration to mean soil concentration for these homes was 65%, suggesting that the Model default of 70% may not be inappropriate for Sandy.

4.0 GEOMETRIC STANDARD DEVIATION

4.1 Use of sliding box approach to estimating blood lead GSD

The sliding box method is not a standard approach and is not recommended for two reasons: 1) the count data in different overlapping soil lead and dust lead boxes were not independent (the replication of blood lead levels was not random) and 2) data were omitted, that is, the boxes with "odd" sides for soil lead or dust lead boxes did not completely cover the data set. One set of boxes has "even" sides, with dust lead or soil lead concentrations in the intervals 0-200, 200-400, 400-600, 600-800, 800-1000, 1000-2000, and >2000 μg/g. This covers all possible values of blood lead. The "odd" set of intervals is 100-300, 300-500, 500-700, 700-900, 1000-2000, and >2000 μg/g. The "odd" set excludes concentrations in the ranges 0-100 and 900-1000 μg/g. These exclusions affect the sample size in each box, as shown in Table 4.

The memorandum in Appendix D of the risk assessment report (pages 15A-15D), allows assessment of all combinations of "even" and "odd" sides. Counts within these boxes show considerable variation, as do the calculated log GSDs for each of the four combinations of sides, as shown in Tables 5 through 8. Tables 5 to 8 also show that most of the blood lead observations are in the lowest dust and soil lead boxes, which typically have the largest variability (standard deviation of log blood lead). Two weighted GSDs were calculated for each table, using the degree-of-freedom-weighted median and the degree-of-freedom-weighted variance estimates. These were converted to GSD values from GSD = exp(SD of log Blood Pb). The results are shown in Table 9.

In view of the heavy weights on the larger GSD estimates in the smaller soil-lead and dust-lead boxes, whatever the split of the concentrations shown in Tables 5 through 8, the TRW recommended departing from the simple unweighted median suggested in the Guidance Manual (U.S. EPA, 1994) and using the weighted estimates in the two right columns of Table 8 (the median is 1.60). The larger estimates from the weighted GSDs clearly do a better job of representing blood lead variability for most of the children exposed to soil lead levels less than 1000 μg/g and dust lead levels less than 500 ppm.

4.2   Recommendation for geometric standard deviation

The site-specific blood lead data do not provide strong support for departing from the default individual GSD of 1.6.

Table 4. Sample Sizes for Boxes with "Even" and "Odd" Sides

Soil Lead Box Side	Dust Lead Box Side	Sample Size

"Even"	"Even"	105
"Even"	"Odd"	96
"Odd"	"Even"	102
"Odd"	"Odd"	91

Table 5. Log GSD and Sample Size for "Even" Soil Lead and "Even" Dust Lead Boxes

Soil Lead (ppm)	Dust Lead (ppm)						
	0-200	200-400	400-600	600-800	800-1000	1000-2000	>2000
0-200	0.64 (17)	0.44 (10)	--	--	--	--	--
200-400	0.47 (21)	0.40 (10)	0.12 (2)	-- (10)			--
400-600	0.32 (3)	0.43 (10)	--	-- (1)	0.10 2		--
600-800	0.47 (3)	0.44 (4)	-- (2)	--	--	-- (1)	--
800-1000	--	0.35 (4)	-- (1)	--	--	--	--
1000-2000	-- (1)	0.26 (3)	0.19 (3)	0.17 (2)	--	--	0.14 (2)
>2000	--	0.39 (2)	--	-- (1)	--	--	--

Sample size shown in parentheses, "--" indicates the GSD was not calculated

Table 6. Log GSD and Sample Size for "Even" Soil Lead and "Odd" Dust Lead Boxes

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Soil Lead (ppm)	Dust Lead (ppm)						
	0-100	100-300	300-500	500-700	700-900	1000-2000	2000+
0-200	--	0.65 (17)	0.38 (3)	--	--	--	--
200-400	--	0.43 (25)	0.31 (6)	--	--	--	--
400-600	--	0.50 (10)	0.26 (3)	-- (1)	0.10 (2)	--	--
600-800	--	0.38 (5)	0.87 (3)	--	--	-- (1)	--
800-1000	--	--	0.30 (5)	--	--	--	--
1000-2000	--	0.29 (2)	0.28 (2)	0.17 (2)	--	--	0.14 (2)
>2000		- 1	0.39 2	- 1			

Sample size shown in parentheses, "--" indicates the GSD was not calculated.

Table 7. Log GSD and Sample Size for "Odd" Soil Lead and "Even" Dust Lead Boxes

Soil Lead (ppm)	Dust Lead (ppm)						
	0-200	200-400	400-600	600-800	800-1000	1000-2000	>2000
0-100	--	--	--	--	--	--	--
100-300	0.57 (33)	0.41 (13)	--	--	--	--	--
300-500	0.66 (8)	0.42 (15)	0.12 (2)	0.89 (2)	-- (1)	--	--
500-700	0.31 (2)	0.36 (2)	-- (1)	--	-- (1)	-- (1)	--
700-900	-- (1)	0.42 (6)	--	--	--	--	--
1000-2000	-- (1)	0.26 (3)	0.19 (3)	0.17 (2)	--	--	0.14 (2)
>2000	--	0.39 (2)	--	-- (1)	--	--	--

Sample size shown in parentheses, "--" indicates the GSD was not calculated.

Table 8. Log GSD and Sample Size for "Odd" Soil Lead and "Odd" Dust Lead Boxes

Soil Lead (ppm)	Dust Lead (ppm)						
	0-100	100-300	300-500	500-700	700-900	1000-2000	>2000
0-100	--	--	--	--	--	--	--
100-300	--	0.56 (33)	0.31 (4)	--	--	--	--
300-500	--	0.52 (19)	0.37 (6)	-- (1)	-- (1)	--	--
500-700	--	0.31 (2)	0.77 (3)	--	-- (1)	-- (1)	--
700-900	--	0.43 (3)	0.51 (4)	--	--	--	--
1000-2000	--	0.29 (2)	0.28 (2)	0.16 (4)	--	-- (1)	0.14 (2)
>2000	--	- (1)	0.39 (2)	-- (1)	--	--	--

Sample size shown in parentheses, "--" indicates the GSD was not calculated.

Table 9. GSD Estimates Using Four Data Splits and Three Methods

Soil Lead Box Sides	Dust Lead Box Sides	Unweighted Median GSD	Weighted Median GSD	Weighted Variance GSD
"Even"	"Even"	1.45	1.55	1.59
"Even"	"Odd"	1.36	1.52	1.65
"Odd"	"Even"	1.46	1.54	1.61
"Odd"	"Odd"	1.45	1.68	1.66